RULES
OF
TIM TENNESSEE DEPARTMENT OF HEALTH AND ENVIRONMENT
BUREAU OF MEDICAL ASSISTANCE-DIVISION OF MEDICAID

CHAPTER 1200-13-2
COMMUNITY HEALTH CLINICS

TABLE OF CONTENTS

1200-13-2-.01 DEFINITIONS.

(1) Community Health Clinic- "Community Health Clinic" means any institution, place, building, or agency represented and held out to the public as ready, willing, and able to furnish medical care, accommodations, facilities, and equipment for use in connection with the services, under the direction of a licensed physician, for persons who may be suffering from deformity, injury, or disease or from any other condition for which nursing or medical services would be appropriate for care, diagnosis, or treatment on an ambulatory basis. Community Health Clinics shall make available a wide range of primary diagnostic and treatment services for all individuals within the service area. The scope of service must be realistic and reflect concern for both quality of care and financial feasibility. The Department has the responsibility to certify Community Health Clinics for participation in state and federally funded programs that are in compliance with the following standards and regulations.

(2) Commissioner- "Commissioner" means the Commissioner of the Tennessee Department of Health and Environment or his designated representative.

(3) Department- "Department" means the Tennessee Department of Health and Environment.

(4) Registered Nurse- "Registered Nurse" means a professional nurse as defined by *T.C.A. §63-740* and licensed in accordance with *TC.A. §63-729. et seq.*

(5) Licensed Practical Nurse -"Licensed Practical Nurse" means a practical nurse as defined by T.C.A.§63-7-108 and licensed in accordance with *TC.A. §63-7-101 et seq.*

(6) Medical Services- "Medical Services" are preventive services and those services rendered for the specific purpose of diagnosing and treating illness, alleviating pain, or rehabilitating deficiencies existing in patients.

(7) Medical Staff- "Medical Staff"' is defined as an organized body composed of one or more physicians currently licensed to practice in the State of Tennessee.

(Rule 1200-13-2-.01, continued)

(8) Ambulatory Patient- "Ambulatory Patient" shall include any person who is not currently being treated in a hospital.

(9) Physician- "Physician" means an individual who is licensed to practice medicine and surgery in the State of Tennessee.

(10) Provider - "Provider" means any person, institution, agency business concern providing medical care services or goods authorized under Title XIX, Chapter XIV, Tennessee Code Annotated, holding, where applicable, a current valid license to provide such services or to dispense such goods.

(11) "Protocols" are written agreements between the physician(s) and physician's assistant(s), and registered nurse(s), and licensed practical nurse(s), or medical student delegating medical tasks for the assessment and management of patient's conditions.

(12) "Supervisions, control and responsibility" shall mean that the physician in charge shall be fully responsible for insuring that quality medical care is being rendered at all times.

(13) "Medical Student" means an individual presently enrolled in a medical school accredited by the Association of American Medical Colleges.

(14) "Physician's Assistant" means an individual who renders services, whether diagnostic or therapeutic, which are acts constituting the practice of medicine, and, but for the provisions of T.C.A. §63-6-204, could only be performed by a licensed physician.

(I5) "Clinic Visit" means a face-to-face encounter between a clinic patient and a physician, physician assistant, nurse practitioner, nurse midwife, specialized nurse practitioner in the Community Health Clinic facility. Encounters with more than one health professional, and multiple encounters with the same Health professional, which take place on the same day and at a single location constitute a single visit, except for, cases in which the patient, subsequent to the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

(16) "Home Visit" means face-to-face encounters by physicians or physician extenders, i.e., physician assistants, licensed nurses, in the place of residence of a recipient. These visits shall be limited to two (2) per recipient during the fiscal year. These visits are reimbursable only and limited to situations where the recipient cannot come into the clinic due to unusual circumstances, i.e. a patient who is acutely ill, unable to drive and has no one else to transport him. Such visits should be initiated by client. All situations must be clearly documented in the record as to the necessity for seeing patients in the home rather than in the clinic.

(17) "Ambulatory Surgical Center (ASC)" means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA under Medicare to participate as an ambulatory surgical center, and meets the conditions set out in the October 1, 1986 edition, Subpart B of 42 CFR 416 in effect as of July 1, 1988.

(18) "Covered Surgical Procedures" means those surgical and other medical procedures which meet the criteria specified in the October 1, 1986, edition of 42 CFR 416. These procedures are published in the April 21, 1987 Federal Register pages 13178-13209 Vol. 52 No. 76.

(19) "Facility Services" means items and services furnished by an ambulatory surgical center in connection with a covered surgical procedure as specified in the October 1, 1986 edition of 42 CFR 416.61.

(Rule 1200-13-2-.01, continued)
***Authority**: T.C.A. §§14-23-105, 14-23-109, 71-5-105, 71-5-109 and 4-5-202.* ***Administrative History**: Original rule filed January 18, 1979, effective March 5, 1979. Amendment filed March 8, 1983; effective April 7, 1983. Amendment filed June 23, 1983; effective July 25, 1983. Amendment filed March 8, 1984; effective June 12, 1984. Amendment filed June 2, 1988, effective July 17, 1988.*

1200-13-2-.02 CERTIFICATE OF AUTHORITY.

(1) In order to qualify as a provider, a Community Health Center must obtain a certificate of authority from the Department.

***Authority**. T. C.A. §14-1905.* ***Administrative History**: Original rule filed January18,1979; effective March 5,1979.*

1200-13-2-.03 APPLICATION, ISSUANCE, AND RENEWAL.

(1) An applicant shall submit a completed application on a form prepared and furnished by the Department. The application shall contain the name of the provider, the person in charge of the clinic, the type of patient to be served, the location of the facility, the physician in charge, the charge nurse, the names and official capacity of the governing body and such other information as the Department may require.

(2) A certificate of authority will be issued by the Department to Community *Health Clinics* determined by the Department to be qualified under Chapter XVI, Title XIX, *T. C.A.* and under these regulations. The renewal of a Community Health Clinic certificate of authority shall be contingent upon continued compliance with said statutes and regulations. Certification under these rules shall be renewed annually. Such renewal date shall take place concurrent with the expiration of the term of the previous provider contract.

(3) Prior to issuance of a certificate, a representative from the Department will inspect the facility for compliance with Conditions of Participation. The survey shall be conducted to evaluate whether the clinic qualifies as a provider; and if it does not comply, what will be necessary for the applicant to qualify under applicable statutes and regulations. Resurveys shall be conducted periodically to substantiate that the clinic has continued to comply with these regulations and standards prior to annual renewal of certification. Initial surveys shall be scheduled; all others shall be unscheduled.

***Authority**: T. C.A. §§14-23-105 and 14-23-109.* ***Administrative History**: Original rule filed January 18, 1979; effective March 5, 1979. Amendment filed March 8, 1983; effective April 7, 1983. Amendment filed June 23, 1983; effective July 25, 1983.*

1200-13-2-.04 CONDITIONS OF PARTICIPATION FOR COMMUNITY HEALTH CLINICS EXCEPT AMBULATORY SURGICAL CENTERS.

(1) Location

(a) The site for a Community Health Clinic should be easily accessible for the patient, staff and personnel.

(2) Building Requirements

(a) The building and equipment shall be conducive to effective patient care and shall comply with the appropriate state and local building fire safety codes and local zone codes.

(b) There shall be at least one restroom. Restrooms shall be accessible to all handicapped patients and/or staff.

(Rule 1200-13-2-.04, continued)

(c) The clinic shall have distinct area used for waiting, with separate enclosed treatment, and/or examining rooms to ensure the privacy of the patient.

(d) The clinic shall have all areas accessible to the handicapped (parking, ramps, handrails and etc.).

(3) Building Safety

(a) There shall be at least one (1) fire extinguisher conveniently located on each floor of the building and in special hazard areas, such as radiology services or laboratory services, where applicable.

(b) The clinic shall develop a fire plan that will be posted and communicated to the staff. All fire exits shall be marked for easy identification.

(4) Management

(a) There shall be a person specified by the clinic who shall have the authority and responsibility for the management, control, and administration of the clinic.

(b) An adequate accounting system shall be maintained as required by the Comptroller’s office.

(5) Staff

(a) Medical personnel employed and health services delivered in a Community Health Clinic shall be under the medical supervision, control, and responsibility of a physician currently licensed in the State of Tennessee. The physician shall visit the clinic as required to insure good quality care.

(b) All personnel, medical and others , shall be licensed to perform the services they render when such services require licensure under the laws of the State of Tennessee.

(c) When medical services are to be rendered in a clinic, either a physician's assistant, a registered nurse, medical student, or physician shall be present on the premises.

(d) There shall be an established patient referral system both within the center and to hospitals and other health care providers.

(e) The authority, responsibility, and function for each category of staff shall be clearly defined in the form of written policies and job descriptions.

(6) Protocols

(a) The licensed physician(s), and physician's assistant(s), and registered nurse(s), and licensed practical nurse(s) or medical student(s) shall jointly develop their protocol for management of medical conditions. The physician(s) shall make certain that the protocol conforms with good medical practice and shall update and review the protocol periodically, at least annually, with the physician's assistant(s), registered nurse(s) or medical student(s). The protocols shall be on rile at the facility at all times.

(b) Written procedures for the Community Health Clinic jointly developed by the physician(s). and physician's assistant(s), and registered nurse(s) and medical student(s) and licensed practical nurse(s) shall outline medical tasks to be used in patient care and the appropriate personnel to be delegated specific tasks. Criteria and procedures for patient referral shall be jointly agreed upon by the physician(s), the physician's assistant(s), the registered nurse(s), the licensed practical nurse(s) or the medical student(s). These criteria and procedures will be part of the protocol.

(7) Medical and Nursing Service

(Rule 1200-13-2-.04, continued)

(a) The performance of medical and nursing procedures shall be accomplished by a registered nurse, licensed practical nurse, physician's assistant, full time medical student, or physician. All procedures performed by either a registered nurse, licensed practical nurse, physician's assistant or medical student shall be under the supervision, control and responsibility of a licensed physician.

(b) All medical and/or nursing functions performed on patients shall be recorded in the patient's medical record, dated, and signed by the person performing the function.

(8) General Standards

(a) The Community Health Clinic shall be in compliance with all applicable federal and state statutes and rules and regulations.

(b) All patient treatments shall be performed by appropriate professional personnel of other personnel as designated by protocol.

(c) Unlicensed workers performing or providing patient care shall be under the direct supervision of a registered nurse or physician.

(d) Adequate medical records shall be kept on every patient. A filing system of medical records shall be established and maintained, and be available for audit and inspection by authorized Department personnel during normal business hours. The broad disease categories of the *International Classification of Diseases. 9th Revision. Clinical Modification* Volumes 1 - 3 shall be used in auditing.

(e) Community Health Clinic records shall include at least:

1. A logbook listing the patient visits to the clinic.

2. Individual patient record;

(i) History of complaints

(ii) Results of appropriate examinations

(iii) Diagnosis, prognosis, and patient disposition prior to treatment

(iv) Treatment ordered

(v) Details of treatment rendered

(vi) Instructions to the patient

3. Pharmacy log

(f) A summary presenting history, diagnosis, and significant outpatient treatment shall be provided any hospital in which a patient is hospitalized for a condition related to the outpatient treatment.

(g) All service, including but not limited to medical services, performed on patients shall be recorded in the patient's medical record, dated, and signed by the person performing the function.

(h) With respect to reimbursement, the Community Health Clinic shall provide all information as required by the Department on forms to be supplied by the Department.

(Rule 1200-13-2-.04, continued)

(i) A record shall be developed for each person which shall include diagnosis, nursing assessments and plan, test results, laboratory findings, and drugs prescribed, disposition of patient problem noted and any other pertinent information about the patient's condition; and the record shall be signed by the person in the clinic providing the services. A signature, or at least a stamped signature, shall be required on laboratory and radiology procedures done external to the clinic.

(j) The responsible physician shall formulate policies and procedures for the clinic staff to follow in case a patient has or develops an emergency condition. An emergency kit, complete with minimum life support equipment, shall be available for instant use in the case of an emergency.

(k) The physician or, in his absence, the registered nurse is responsible for reporting infectious and contagious diseases in accordance with current Department regulations.

(l) A quality assurance program shall be instituted by the clinic staff and a physician, including regular audits of patient records and peer review according to accepted standards and criteria.

***Authority**: T.C.A. §§14-1905, 14-23-105, 14-23-109, 71-5-105, 71-5-109 and 4-5-202.* ***Administrative History**: Original rule filed January 18, 1979, effective March 5, 1979. Amendment filed March 8, 1983; effective April 7, 1983. Amendment filed March 8, 1984, effective June 12, 1984. Amendment filed June 2, 1988, effective July 17, 1988.*

1200-13-2-.05 CONDITION OF PARTICIPATION FOR COMMUNITY HEALTH CLINICS CLASSIFIED AS AMBULATORY SURGICAL CENTERS (ASC).

(1) Compliance with State Licensure Law

(a) The ASC must comply with state licensure requirements.

(2) Governing Body and Management

(a) The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment.

(3) Hospitalization

(a) The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(b) The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

(4) Surgical Services

(a) Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(b) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(c) Anesthetics must be administered by only:

(Rule 1200-13-2-.05, continued)

1. A qualified anesthesiologist; or

2. By an anesthetist under the supervision of the operating physician.

(d) All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(5) Environment

(a) The ASC must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients.

(b) The ASC must provide a functional and sanitary environment for the provision of surgical services.

1. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

2. The ASC must have a separate recovery room and waiting area.

3. The ASC must establish a program for identifying and preventing infections, maintaining a environment, and reporting the results to appropriate authorities.

(c) The ASC must meet the provisions of state and local building fire safety codes and local zone codes.

(d) Emergency equipment available to the operating rooms must include at least the following:

1. Emergency call system.

2. Oxygen.

3 . Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

4. Cardiac defibrillator.

5. Cardiac monitoring equipment.

6. Thoracotomy set.

7. Tracheostomy set.

8. Laryngoscopes and endotracheal tubes.

9. Suction equipment.

10. Emergency drugs and supplies specified by the medical staff.

(e) Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

(6) Medical Staff

(Rule 1200-13-2-.05, continued)

(a) The medical staff of the ASC must be accountable to the governing body.

(b) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(c) Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(d) If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

(7) Nursing Services

(a) The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(b) Patient care responsibilities must be delineated for all nursing service personnel.

(c) Nursing services must be provided in accordance with recognized standards of practice.

(d) There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(8) Medical Records

(a) The ASC must develop and maintain a system for the proper collection, storage and use of patient records.

(b) The ASC must maintain a medical record for each patient. Every record must be accurate, legible and promptly completed. Medical records must include at least the following:

1. Patient identification.

2. Significant medical history and results of physical examination.

3. Pre-operative diagnostic studies (entered before surgery), if performed.

4. Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

5. Any allergies and abnormal drug reactions.

6. Entries related to anesthesia administration.

7. Documentation of properly executed informed patient consent.

8. Discharge diagnosis.

(9) Pharmaceutical Services

(Rule 1200-13-2-.05, continued)

(a) The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

(b) Drugs must be prepared and administered according to established policies and acceptable standards of practice.

1. Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

2. Blood and blood products must be administered by only physicians or registered nurses.

3. Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(10) Laboratory and Radiologic Services

(a) The ASC must have procedures for obtaining routine and emergency laboratory and radiologic services, from Medicare approved facilities, to meet the needs of patients.

(11) The ASC shall provide all information as required by the Department on approved forms.

Authority: *T.C.A. §§71-5-105, 71-5-109 and 4-5-202.* ***Administrative History****: Original rule filed January 18, 1979. Rule renumbered as 1200-13-2-.06. New rule filed June 2, 1988; effective July 17, 1988.*

1200-13-2-.06 REVOCATION, SUSPENSION, OR CORRECTION OF DEFICIENCIES.

(1) Upon finding that a Community Health Clinic has failed to meet any applicable statutes or regulations adopted pursuant thereto, the Commissioner or his designee may order such violations or deficiencies corrected; in addition, he may suspend the certificate of authority in accordance with T.C.A. §14-1905(3), et. seq., and pursuant to rules and regulations promulgated thereto by the Tennessee Department of Public Health. All proceedings thereunder shall be conducted pursuant to T.C.A. §4-507, et seq., and rules and regulations promulgated by Tennessee Department of Public Health.

(3) If it appears from the charges or answers that the Commissioner or his designee must decide upon issues involving standards of good medical practice or proper supervision by physicians, the Commissioner or his designee may request the advice of the Medical Care Advisory Committee as authorized by T.C.A. §14-1921 prior to making such decisions.

Authority*: T. C.A. §§14-1905, 71-5-105, 71-5-109 and 4-5-202.* ***Administrative History****: (Formerly numbered as 1200-13-2-.05.) Original rule filed January 18, 1979. Amendment filed June 2, 1988; effective July 17, 1988.*

1200-13-2-.07 REIMBURSEMENT FOR COMMUNITY HEALTH CLINICS EXCEPT AMBULATORY SURGICAL CENTERS.

(1) Determination of Reimbursable Costs for The Community Health Clinic-The Department, in consultation with the Comptroller of the Treasurer, shall establish rules and regulations for the determination of reimbursable cost per patient visit for the community health clinics.

(2) Exclusion of Organization or Clinics or Parts Thereof Which Can Be Classified As another Type of Facility -

(a) If any community health clinic or any part of such organization meets the Medicaid Program definition for another provider type, other than a pharmacy, which is provided for in another

(Rule 1200-13-2-.07, continued)

category of service in the Medicaid Program, such clinic or part thereof shall be governed by the rules applicable to that program.

(b) If any community health clinic shall have a pharmacy unit as an integral part, the costs of the pharmacy, including drugs and supplies approved by the Medicaid Program, shall be covered in cost in accordance with these rules and will not be reimbursed based on pharmacy reimbursement rule 1200-13-1-.06(13).

(3) Billing Procedures-The community health clinics shall bill the Department on forms and in the manner designated by the Department.

(4) Limiting Cost to Charges As a Maximum - Reimbursable cost, as provided for in these rules and regulations, shall be limited, as a maximum, to charges to private paying patients for equivalent services, and to charges as verified by the Comptroller of the Treasury for substantially equivalent services prevailing in the area.

(5) Establishment of Interim Reimbursement Rates -The Comptroller of the Treasury will establish interim reimbursement rates for these organizations or clinics. The Comptroller's Office shall consider (a) the charge system of the organization or clinic, (b) budgeted information supplied by the provider, (c) prior cost data, and (d) any other relevant data submitted by the provider and verified by the Comptroller to determine the adequacy of the existing interim percentage of charge rate and where necessary, to set a new more adequate rate.

(6) Submission of Annual Cost Reports By Providers-

(a) All community health clinics will be required at their fiscal year end to submit to the Comptroller of the Treasury or his agent an annual cost report on forms designated by the Department. This report shall be submitted not later than three months from the end of the facility's fiscal year. Such cost report must be completed in accordance with the Medicare-Medicaid principles of cost reimbursement as stipulated in the Medicare Provider Reimbursement Manual effective October 1, 1984. All "covered charges" are to be in accordance with the Medicaid Program definition of covered services. Also, all charges to Medicaid recipients must be made consistently and in accordance with the provider's schedule of charges in effect for the period for all patients.

(b) All community health clinics that do not file cost reports as required in this section in a timely manner shall be subject to the sanctions specified in *T.C.A.* §71-5-130.

(7) Approval of Initial and Final Settlements -

(a) Procedure for Approval of Initial Settlements. -Upon receipt of the information outlined in Paragraph 6, the Comptroller of the Treasury or his agent will review each provider's cost report and compare it with information submitted and certified by the Department or its fiscal agent. On the basis of this comparision and review, the Comptroller's Office will make an initial determination of the amount of cost settlement due the provider or the State for the provider's fiscal year. The approval of the initial settlement will be made subject to further review, audit and/or subsequent finding of the Comptroller of the Treasury or his agent. Both the provider and the Department will be advised of the initial settlement. On the basis of the approved initial settlement, the Department or its fiscal agent will (as may be required) either make arrangements for an additional payment to the provider for services provided during the fiscal year or submit a claim to the provider requesting payment to the Medicaid Program for the amount of overpayment made to the provider during the fiscal year.

(Rule 1200-13-2-.07, continued)

(b) Approval of Final Cost Settlements. - Once such review and/or auditing has been performed by the Comptroller of the Treasury or his agent as is necessary for final cost settlement, the Comptroller's Office will advise the provider and the Department of the final cost settlement approved. On the basis of the approved final settlement the Department or its fiscal agent will (as may be required) either make arrangements for an additional payment to the provider for services provided during the fiscal year or submit a claim to the provider requesting payment to the Medicaid Program for the amount of overpayment made to the provider during the fiscal year.

(8) Annual Certification of Covered Charges, Interim Payments, and Patient Days of Care to the Comptroller's Office. - Not later than four months after the end of a provider's fiscal year, the Department or its fiscal agent shall certify to the Comptroller of the Treasury or his agent the following information:

(a) Amount of covered charges reimbursed and approved by the Medicaid Program during the provider's last fiscal period accumulated to each of the various "ancillary" and "routine" charge centers.

(b) Amount of reimbursement paid by the Medicaid Program to the provider for the fiscal period.

(c) The number of occasions of service or visits covered, reimbursed and approved by the Medicaid Program during the provider's last fiscal year.

Authority: *T.C.A. 14-23-105,14-23-109,14-23-130,14-23-201,71-5-105,71-5-109 and 4-5-202.* ***Administrative History:*** *(Formerly numbered as 1200-13-2-.06). Original rule filed June 25, 1985; effective July 25,1985. Amendment filed June 2, 1988, effective July 17, 1988. Amendment filed January 30, 1989; effective March 16, 1989.*

1200-13-2-.08 TERMINATION OF MEDICAID COMMUNITY HEALTH CLINICS RULES. For services provided prior to January 1, 1994, the rules as set out at 1200-13-2 shall apply. Effective January 1, 1994, the rules of TennCare as set out at rule chapter 1200-13-12 shall apply. Medicaid will continue to pay Medicare premiums, deductibles and copayments in accordance with the Medicaid rules in effect prior to January 1, 1994, and as may be amended.

Authority. *T.C.A. §§4-5-202, 71-5-105, 71-5-109 and Public Chapter 358 of the Acts of 1993.* ***Administrative History****: Original rule filed June 2,1988; effective July 17,1988. Repeal filed June 22,1989; effective August 4,1989. Amendment filed March 18, 1994; effective June 1, 1994.*